

## REMARKS

### Status of the Claims

Claims 1-6, 8-10, 12-15, 17-23, 25-27, 29-45 are currently pending.

Claims 1-6, 8-10, 12-15, 17-23, 25-27, 29-45 stand rejected.

Claims 1-17, 35-38, 41-42, 44 are cancelled herein.

Claims 18 and 39 are amended herein and 46-67 are newly added herein. No new matter has been introduced.

### Claim Rejections

In the November 14, 2008 Examiner's Answer ("Examiner's Answer"), the Examiner issued a new ground of rejection for claims 1-15, 17, 35-38, 41-42, and 44 under 35 U.S.C. § 101. In the Examiner's Answer and the final office action issued February 11, 2008 ("Final Office Action"), claims 1-6, 8-23, 25-27, and 29-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999* ("Ware et al."), in view of U.S. Patent No. 5,059,127 to Lewis ("Lewis"). In the Examiner's Answer and the Final Office Action, claims 42-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ware et al, in view of U.S. Patent No. 6,067,523 to Bair ("Bair"). Applicants respectfully traverse these rejections.

### 35 U.S.C. § 101 Rejection

In the Examiner's Answer, the Examiner issued a new ground of rejection for claims 1-15, 17, 35-38, 41-42, and 44 under 35 U.S.C. § 101. Applicants cancel claims 1-15, 17, 35-38, 41-42, 44 herein and therefore render this rejection moot. Accordingly, applicants request that this rejection be withdrawn.

### 35 U.S.C. § 103 Rejection: Ware in view of Lewis

All currently pending claims 18-23, 25-27, 29-34, 39-40, 43, 45-67 require "varying a threshold as a function of said estimated score during administration of said test to said

patient.” Neither Ware nor Lewis either taken alone or in combination teaches this limitation. Applicants note that the Examiner erroneously asserts that Applicants argue that Ware in view of Lewis teaches “varying a threshold as a function of said estimated score.” (Examiner’s Answer at 13). Applicants expressly oppose this error. Applicants have never stated that Ware in view of Lewis teaches this limitation. To the contrary, Applicants have repeatedly and consistently argued that Ware in view of Lewis *does not* teach the limitation of “varying a threshold as a function of said estimated score.” (*See, e.g.*, 08/26/2008 Appeal Brief at 11, 13-16).

Applicants submit that Ware describes a health assessment method that utilizes a fixed, unvarying, set or preset standards of precision within a single health assessment, whereas the present invention provides a method of assessing the health status or health care of a patient wherein the threshold varies as a function of the estimated score within or during the administration of a single test. The Examiner even admits that Ware does not expressly describe “varying a threshold as a function of said estimated score.” (Examiner’s Answer at 6). Somewhat inconsistently, however, the Examiner also continues to assert that

[a]s per the recitation of “the threshold varying as a function of the estimated score,”: Ware discloses the following steps in Figures 3: step 3) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of “threshold”), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient’s score (see page 12, col. 1-2). . . . Note, Ware’s discussion of where the preset standard of precision is +/-5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, Ware discloses that the standard of precision was relaxed to +/-7.9 or less for patients at or above the 90<sup>th</sup> percentile.

(Examiner’s Office Action at 6-7; *see also* Final Office Action, pages 3-4) (emphasis added).

Contrary to the Examiner's assertions, neither this passage of Ware nor any other portion of it describes that the threshold varies during the administration of a single test. "Re-estimating the score" and "re-estimating the confidence level" does not affect or change the *constant* "preset standard of precision" (i.e., threshold) to which the variable score and confidence level are compared. In fact, the prior Examiner who was responsible for the August 3, 2007 Office Action, even admitted therein that Ware is deficient because it does not describe "varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold" (August 3, 2007 Office Action at 3).

The passages cited by the current Examiner in the Examiner's Answer and in the Final Office Action merely show that Ware sets different precision standards for different groups of patients (low vs. high scoring patients). In fact, these passages from Ware cited by the Examiner clearly support applicants' position that Ware does not describe varying the threshold during the administration of a single test to a single patient. Contrary to the Examiner's assertion on page 14 of the Examiner's Answer, setting different "preset" precision standards for different groups of patients (low vs. high scoring patients) is not varying a threshold *during the administration of a test of a patient*.

Moreover, applicants respectfully submit that one of ordinary skill in the art would not find that modifying the different preset precision standards in Ware, which are *fixed* for different groups of patients (low vs. high scoring patients), is equivalent to varying the threshold during the administration of a single test to a single patient as a function of the estimated score as required by claims 18-23, 25-27, 29-34, 39-40, 43, 45-67. Therefore, the Examiner has failed to show that Ware teaches varying the threshold as a function of the estimated score during that administration of a test to a patient.

Lewis does not teach or suggest "varying a threshold *as a function of said estimated score during the administration of said test to said patient*" as required by all the claims of the present invention (emphasis added). While Lewis teaches "assigning variable threshold variables to particular testlets," as cited by the Examiner, (Examiner's Answer at 7; Final Office Action at 4), Lewis does not teach or suggest varying a threshold "*as a function of said estimated score during administration of said test to said patient*" as required by the claims.

Accordingly, Lewis does not cure the aforementioned deficiency in Ware. Lewis teaches assigning variable threshold variables generally in the context of preparing a *random* testlet selection (see, e.g., Lewis, col. 9, lns. 6-9). This is diametrically opposed to “varying a threshold *as a function of said estimated score*” which is based on adjusting a threshold “on the fly” during the administration of the test. Further, Lewis actually teaches away from an *adaptive* testing method by disparaging such a method as complicated and not easily implemented. (see e.g., Lewis, col. 8 ln. 61 – col. 9, ln. 13). For example, Lewis states that “the primary reasons for selecting *random* rather than *adaptive* [include] (i) computational efficiency: . . (ii) simplicity . . . ; [and] (iii) ease of implementation”; Lewis also states that “the additional complication of an adaptive testlet selection mechanism is . . . *not particularly desirable*.” (see e.g., Lewis, col. 8 ln. 61 – col. 9, ln. 13). As such Lewis actually teaches away from the testing method of the claims of the present invention which require varying a threshold “as a function of said estimated test score.” The prior art must to be judged based on a full and fair consideration of what that art teaches, not by using applicants’ invention as a blueprint for gathering various bits and modifying the pieces in an attempt to reconstruct applicant’s invention. The operation of the reference cannot be changed or the reference rendered inoperable for its intended purpose simply to invalidate the claims.

Moreover, while the Examiner cites *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) and quotes “*In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006)” (Final Office Action at 12) to point out that rejections on obviousness “need not seek out precise teachings directed to the specific subject matter,” applicants also stress the United States Supreme Court *warning* in *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) that:

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See *Graham*, 383 U. S., at 36 (warning against a ‘temptation to read into the prior art the teachings of the invention in issue’ and instructing courts to ‘guard against slipping into the use of hindsight’ . . .)

“To imbue one of ordinary skill in the art with knowledge of the present invention, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim of the

insidious effect of hindsight syndrome, wherein that which only the inventor taught is used against the teacher.” *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983).

. Nowhere do Ware or Lewis solely or in combination teach “varying a threshold *as a function of said estimated score during administration of said test to said patient*” as required by claims 18-23, 25-27, 29-34, 39-40, 43, 45-67. Thus, because these references do not teach all the claim limitations alone or in combination, they cannot render the claims obvious.

### 35 U.S.C. § 103 Rejection: Ware in view of Bair

Bair also fails to teach or suggest “varying a threshold *as a function of said estimated score during administration of said to said patient*” and “dynamically modifying said test during the administration of said test to said patient based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold” as required by claims 18-23, 25-27, 29-34, 39-40, 43, 45-67. Bair merely describes generating a test from a master question table and skipping certain related questions based on the answer to the first related question. *See* col. 11, line 45 - col. 13, line 12. For example, if the patient answers that she has no history of drug abuse, then the drug related questions (i.e., what drugs are you taking) will be skipped. There is no disclosure in Bair related to use of a threshold as a function of the estimated score during the administration of a test to a patient. Nowhere do Ware (as explained above) and Bair, solely or in combination teach “varying a threshold *as a function of said estimated score during administration of said test to said patient*” and “dynamically modifying said test during the administration of said test to said patient based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold” as required by all the claims of the present invention. Accordingly, the addition of Bair does not cure the afore-explained deficiency of Ware, and the combination of Ware and Bair does not teach or suggest varying the threshold as a function of the estimated score as required by claims 18-23, 25-27, 29-34, 39-40, 43, 45-67. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness based on the combination of Ware and Bair.

There Is No Reasonable Expectation of Success By Combining the References

There is also no reasonable expectation of success in achieving the invention by combining Ware, Lewis, and Bair. With respect to the combination of Ware and Lewis, as explained above, Lewis is directed to a mastery system that teaches away from an adaptive test method wherein the threshold value is based on a specific element. Moreover, neither Ware, Lewis, nor Bair suggest the desirability of the claimed invention because Ware, Lewis and Bair are not even remotely concerned with the problem of providing flexibility in the administration of a health test by emulating the evaluation process performed by a professional health care provider. Typically, the health care provider administering the test may inquire more deeply into certain issues (related to specific domains) raised by the patient's answer if the patient scored poorly, whereas additional questions related to domains which are of reduced interest would not be asked. For example, if a person has difficulty walking up the stairs due to leg pain without shortness of breath or chest pain, a health care provider will want to gather more information regarding the leg pain. This could be done by more focused questions directed to the history of the leg pain, e.g., how long have you had the pain, how severe is the pain on a scale of 1-10, when does it hurt the most, and by ordering further tests like an x-ray or MRI. The health care provider will not inquire further regarding possible issues related to shortness of breath or chest pain, because it was found out that this is not the reason that the patient is having difficulty walking up the stairs.

The present invention provides such flexibility by varying the threshold as a function of the estimated score during the test. In particular, during the administration of the test, the threshold will be raised for a domain of particular interest and will be lowered for a domain of lesser interest. In so doing, the present invention streamlines the process by not requiring an unnecessary amount of additional questions for domains which are of reduced interest, while requiring an increased number of questions related to a domain of particular interest. This advantage of the present invention raises the statistical accuracy and relevancy of the test, while at the same time reducing the burden on the test subject. It is undeniable that neither Ware, Lewis, nor Bair individually or in combination therewith are even remotely

concerned with providing such flexibility. Since applicants have recognized a problem not addressed by the cited prior art and solved that problem in a manner not suggested by cited prior art, the basis for patentability of the claims is established. *See In re Wright*, 6 U.S.P.Q. 2d, 1959, 1961-1962 (Fed. Cir. 1988). There, the CAFC relied upon previous decisions requiring a consideration of the problem facing the inventor in reversing the Examiner's rejection. "The problem solved by the invention is always relevant." *Id.* at 1962. *See also, In re Rinehart*, 189 U.S.P.Q. 143, 149 (CCPA 1967), which stated that the particular problem facing the inventor must be considered in determining obviousness.


Therefore, Ware, Lewis, or Bair independently or in combination do not teach or suggest "varying a threshold *as a function of said estimated score during administration of said test to said patient*" and "dynamically modifying said test during the administration of said test to said patient based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold" as required by all the pending claims. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claims 18-23, 25-27, 29-34, 39-40, 43, 45-67 based on Ware, Lewis, or Bair independently or in combination.

In summary, applicants respectfully submits that the cited references independently or in combination fail to teach or suggest all the claim limitations of claims 18-23, 25-27, 29-34, 39-40, 43, 45-67. In view of the above, applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-QMET-201-US (10104949) from which the undersigned is authorized to draw.

Dated: January 12, 2009

Respectfully submitted,

By 

C. Andrew Im

Registration No.: 40,657

FULBRIGHT & JAWORSKI L.L.P.

666 Fifth Avenue

New York, New York 10103

(212) 318-3000

(212) 318-3400 (Fax)

Attorney for Applicants